Essai Clinique

Généré le 27 avr. 2024 à partir de

Titre	A Phase I/Ib Global, Multicenter, Open-label Umbrella Study Evaluating the Safety and Efficacy of Targeted Therapies in Subpopulations of Patients With Metastatic Colorectal Cancer
Protocole ID	INTRINSIC
ClinicalTrials.gov ID	NCT04929223
Type(s) de cancer	Côlon et rectum
Phase	Phase I
Stade	Métastatique
Type étude	Clinique
Médicament	Inavolisib + cétuximab, inavolisib + bévacizumab, atézolizumab + tiragolumab + bévacizumab, atézolizumab + tiragolumab, atézolizumab + SY-5609, GDC-6036 + cétuximab + FOLFOX, GDC-6036 + cétuximab
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL H HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	
Investigateur principal	Dr Petr Kavan
Coordonnateur	Daria Krutauz 514-340-8222 poste 24301
Statut	Actif en recrutement
Date d'activation	12-10-2022
But étude	This open-label, exploratory study is designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or combinations, in participants with metastatic colorectal cancer (mCRC) whose tumors are biomarker positive as per treatment arm-specific definition. Eligible participants with mCRC will be enrolled into specific treatment arms based on their biomarker assay results.
Critères d'éligibilité	• Signed next-generation sequencing (NGS) Biomarker Eligibility Informed Consent Form • Age >= 18 years at time of signing Informed Consent Form • Biomarker eligibility as determined at a College of American Pathologists/clinical laboratory improvement amendments (CAP/CLIA)-certified or equivalently accredited diagnostic laboratory using a validated test • Eastern Cooperative Oncology Group (ECOG) Performance Status of <= 1 • Life expectancy >= 3 months, as determined by the investigator • Histologically confirmed adenocarcinoma originating from the colon or rectum • Metastatic disease • Prior therapies for metastatic disease • Ability to comply with the study protocol, in the investigators judgment • Measurable disease (at least one target lesion) according to Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1) • Availability of an archival tissue sample for exploratory biomarker research • Adequate hematologic and organ function within 14 days prior to initiation of study treatment • For women of childbearing potential: Must have a negative serum pregnancy test result within 14 days prior to initiation of study treatment and agreement to remain abstinent or use contraceptive measures

	• For men: agreement to remain abstinent or use contraceptive measures, and agreement to refrain from donating sperm
Critères d'exclusion	• Current participation or enrollment in another interventional clinical trial • Any systemic anti-cancer treatment within 2 weeks or 5 half-lives (whichever is shorter) prior to start of study treatment • Treatment with investigational therapy within 28 days prior to initiation of study treatment • Pregnant or breastfeeding, or intending to become pregnant during the study • History of or concurrent serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the patient's safe participation in and completion of the study or confounds the ability to interpret data from the study • Severe infection within 4 weeks prior to initiation of study treatment or any active infection that, in the opinion of the investigator, could impact patient safety • Incomplete recovery from any surgery prior to the start of study treatment that would interfere with the determination of safety or efficacy of study treatment • Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures (once monthly or more frequently) • Uncontrolled tumor-related pain • Uncontrolled or symptomatic hypercalcemia • Clinically significant and active liver disease • Known HIV infection • Symptomatic, untreated, or actively progressing CNS metastases • History of leptomeningeal disease or carcinomatous meningitis • History of malignancy other than CRC within 2 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death • Any other disease, unresolved toxicity from prior therapy, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications • Requirement for treatment with any medicinal product that contraindicates the use of any of the study treatments, may interfere with the planned treatment, affects patient compliance, or puts the patient at higher risk for treatment-related complications